510(K) SUMMARY

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**
Advanced Diagnostics Incorporated
8112 304th Avenue SE
Preston, WA 98050
Contact Person:
Steve Hesler
Director of Regulatory Affairs
phone: 425 222 7169
fax: 425 222 7171
Date Prepared:
November 19, 2001

2. **Proprietary Name:**
Avera Model DEI System (Diffractive Energy Imaging)
Common/ Usual Name:
Acoustical Holography Imaging System
Classification Name:
90 NCS

3. **Predicate Device:**
The DEI System is substantially equivalent to the OS-2000 Optical Sonography system cleared via k100150, November 30, 2000 with the addition of real-time image-guided biopsy capability. The biopsy feature in the DEI system is substantially equivalent to the Sonopsy LA System marketed by US Surgical Corp per K980424, cleared August 7, 1998.

4. **Device Description:**
The DEI System is a general purpose, software-controlled, diagnostic ultrasound system that complies with pre-amendment application-specific acoustic output levels (track 1). Its function is to acquire ultrasound data in acoustical holography mode and display it on an LCD monitor.

The DEI System has been designed to meet the following product safety standards:

- UL 2601 – Standard for Medical Electrical Equipment - Part 1: General Requirements for Safety
- ISO 109993 – Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", September 30, 1997.
- "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices", CDRH, 1985.

5. **Intended Uses:**
The DEI System acoustical holography imaging system is intended for the following uses: Small Parts, Pediatrics, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

6. **Technological Comparison to Predicate Device:**
The DEI System is similar to the predicate device (OS-2000, k001510) in that both use an object transducer that is coupled to the patient by use of a water-path (immersion in water bath or use of water bladders) to transmit pulsed ultrasound through the targeted tissues.

These transmitted pulses are then acoustically focused. The focused ultrasound beam is then combined with a second plane wave (reference wave) of the same frequency as the transmit wave. The interaction of the transmit wave and the reference wave creates an interference pattern on a target detector device within the enclosed system, forming an acoustic hologram of the object. The detector is illuminated with a coherent light source (laser) resulting in a visual image. The visual image is recorded with a CCD video camera and the images are displayed on a video monitor. Images may be stored to hard disk. This modification to the predicate involves the addition of biopsy capability.
The Avera is substantially equivalent to a predicate device, the Sonopsy LA System (K 980423) in that both allow real time image-guided biopsy within image guidance in 1 plane and an assist device to locate the plane of focus (depth plane).

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2002

Mr. Steve C. Hesler
Director of Quality and Regulatory Affairs
Advanced Diagnostics, Inc.
8112 304th Ave. SE, Suite B
PRESTON WA 98050

Re: K013886
Trade Name: Avera Model DEI System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 90 NCS
Dated: February 27, 2002
Received: March 1, 2002

Dear Mr. Hesler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Attachment 1

Ultrasound Device Indications Statement

510 (k) Number (if known) : K013886

Device Name : **Avera Model DU System**

Intended Use: Diagnostic ultrasound imaging of human soft tissues

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Acoustic Holography
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Neurosurgical										
Pediatric										P
Small Organ (Specify)										P [1]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										P
Laparoscopic										
Musculo-skeletal Conventional										P
Musculo-skeletal Superficial										P
Other (specify)										N [2]

N = new indication; **P = previously cleared by FDA;** **E = added under Appendix E**

Other Indications or Modes:

1 **Small organ imaging is intended for the breast**

2 **Breast biopsy**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013886

Prescription Use (Per 21 CFR 801.109)